

was placed in Groups 4-22; claims 8 and 9 were placed in Groups 11 and 17; claims 10-12 were placed in Groups 5-10, 12-16, and 18-22; claim 13 was placed in Groups 7, -10, 14-16, and 20-22; claims 14-16 were placed in Groups 1-22; claim 17 was placed in Groups 1, and 4-10; claim 18 was placed in Groups 2, and 11-16; and claim 19 was placed in Groups 3, and 17-22. Finally, independent claims 20 and 26 were placed in multiple groups (Groups 23-25 and 26-27, respectively).

As such, on its face this rejection is improper and should be withdrawn. By placing claims 1-19 in 22 separate groups, claims 20-25 in three separate groups, and claim 26 in two separate groups, the Examiner has improperly attempted both to reject these claims for misjoinder, and to reject the claims on the basis that they allegedly represent independent and distinct inventions. Furthermore, examining the claims together would not place an undue examination burden on the Examiner.

A. An Examiner may not reject a particular claim on the basis that it represents "independent and distinct" inventions

By restricting a single claim and placing it in more than one group, the Examiner is alleging that the single claim represents multiple "patentably distinct" inventions. As such, this type of restriction requirement is a *de facto* rejection of the patentability of the claim, because the claim cannot issue as drafted. As the C.C.P.A. noted:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be

the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification. *In re Weber, Soder and Boksay*, 198 USPQ 328, 331 (C.C.P.A. 1978). *See also In re Haas*, 179 USPQ 623, 624-625 (C.C.P.A. 1973) (*In re Haas I*); and *In re Haas*, 198 USPQ 334, 334-337 (C.C.P.A. 1978) (*In re Haas II*). *See also* MPEP § 803.02.

Moreover, it has long been held that an Examiner may not reject a particular claim on the basis that it represents "independent and distinct" inventions. *See In re Weber*, 198 USPQ at 328. The courts have definitively ruled that the statute authorizing restriction practice, i.e., 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See id.*; *In re Haas I*, 179 USPQ at 623; and *In re Haas II*, 198 USPQ at 334. In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In re Weber*:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-no matter how broad, which means no matter how many independently patentable inventions may fall within it.
In re Weber, 198 USPQ at 334.

As described above, the present invention is the discovery that the protein called "integrin-linked kinase associated protein" ("ILKAP") is involved in modulation of angiogenesis. Applicants have thus claimed three different aspects of this invention: (1) assays for identifying modulations of angiogenesis and ILKAP; (2) methods of treating diseases associated with angiogenesis by administering such ILKAP modulators; and (3) methods of treating diseases associated with angiogenesis by administering protein or nucleic acid encoding ILKAP. Assays for identifying modulators of ILKAP represent a

genus of assays that are described on the basis of common structural and functional features, i.e., the use of ILKAP encoded by a reference nucleic acid. Although the individual species of the genus may also be separately patentable, the genus as a whole represents a single invention. Therefore, rejecting claims 1-19, 20-25, and 26, respectively, for misjoinder is therefore clearly improper. Applicants thus respectfully request that the Examiner withdraw the improper restriction requirement with respect to Groups 1-22, 23-25, and 26, respectively. In particular, Applicants request that the Examiner withdraw the restriction requirement with respect to Groups 1-22, claims 1-19.

B. Examining the claims of Groups 1-22, 23-25, and 26, respectively, together does not place an undue examination burden on the Examiner

Furthermore, restriction of an application is discretionary. A restriction requirement is made to avoid placing an undue examination burden on the Examiner and the Office. Where claims can be examined together without undue burden, the Examiner must examine the claims on the merits even though they are directed to independent and distinct inventions. MPEP § 803.01. Applicants respectfully submit that examining the claims of Groups 1-22 together (assays for identifying modulators of ILKAP for treatment of angiogenesis) would not place an undue burden on the Examiner.

In establishing that an “undue burden” would exist for co-examination of claims, the Examiner *must* show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome. To show undue burden resulting from searching difficulties, the Examiner must show one of the following, as set forth in MPEP § 808.02:

(1) *Separate classification thereof.*

This shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.

(2) *A separate status in the art when they are classifiable together:*

Even though they are classified together, each subject can be shown to have formed a separate subject for inventive effort when an explanation indicates a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.

(3) *A different field of search:*

Where it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.

Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions.

In the present case, the majority of the claims fall into the same class (either class 424, 435, or 514) and in the same subclass (either subclass 6, 7.1, 8, 44, and 120.1). Applicants submit that searching Groups 1-22, corresponding to claims 1-19, places no undue examination burden on the Examiner. Applicants therefore respectfully request that the restriction requirement with respect to Groups 1-22, claims 1-19 be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

USSN 09/935,124

Lorens et al.

Page 6

PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned as indicated below.

Respectfully submitted,

A handwritten signature in cursive script, reading "Annette S. Parent".

Annette S. Parent
Reg. No. 42,058

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: (415) 576-0300
ASP:dk